HELLER EHRMAN WHITE & McAULIFFE
ATTORNEYS
A PARTNERSHIP OF PROFESSIONAL CORPORATIONS

815 CONNECTICUT AVENUE, N.W.
SUITE 200
WASHINGTON, D.C. 20006-4004
TELEPHONE: (202) 785-4747
FACSIMILE: (202) 785-8877

MICHAEL M. LANDA
(202) 530-4341
mlanda@hewm.com

WASHINGTON, D.C.
HONG KONG
SINGAPORE

SAN FRANCISCO
SILICON VALLEY
LOS ANGELES
SAN DIEGO

SEATTLE
PORTLAND
ANCHORAGE

July 28, 1999

DELIVERY BY HAND

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET NO. 98N-1215; 21 CFR PARTS 207, 607, AND 807; FOREIGN ESTABLISHMENT REGISTRATION AND LISTING; PROPOSED RULE

Dear Sir or Madam:

We are submitting these comments on behalf of a foreign-based multinational manufacturer and marketer of FDA-regulated articles.

We are mindful of the fact that Section 510(i) of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), as amended by Section 417 of the Food and Drug Administration Modernization Act of 1997, requires that a foreign establishment that manufactures, prepares, propagates, compounds or processes a device or drug (including a biological product) that is imported or offered for import into the United States must register and list. Our concern is that the proposal would require that each such establishment, on its own, provide registration information; the proposal would not appear to permit, say, the parent of all of a multinational's foreign establishments to register for each of them. By contrast, under the proposal (as under the current regulation) the parent could submit the requisite listing information. This difference in treatment is not required by the law and in any case does not make good sense.

98N-1215

C3

I. THE LAW

Section 510(i) and (j) of the FDCA states that "[a]ny establishment . . . shall" register and that "[e]very person" who registers "shall" list. There is, however, no prohibition against one person or entity registering or listing for more than one establishment, so long as the information applicable to each establishment is clear. Current §§ 207.20(a), 607.20(a), and 807.20(a) explicitly recognize as much for listing, as did § 807.20(c) for registration by device distributors with multiple sites before Congress (in the Modernization Act) exempted such distributors from registration.

Put another way, the language of § 510(i) and (j) of the statute leaves FDA ample room to permit a foreign-based parent to register as well as list for each of its foreign establishments, especially in light of agency interpretations of seemingly *inflexible* statutory provisions. For example, although § 402(a)(3) of the FDCA (21 U.S.C. § 342(a)(3)) provides that a food is adulterated if it consists in whole or *in part* of any filthy, putrid, or decomposed substance, § 402(a)(3) does not require FDA to seek the condemnation and destruction of each and every food that contains de minimis amounts of aesthetic contaminants, *United States v. General Foods Corp.*, 446 F. Supp. 740 (D.C.N.Y. 1978), *aff'd*, 591 F.2d 1332 (2d Cir. 1978). Similarly, although § 406 (21 U.S.C. § 346) provides that FDA "shall promulgate regulations" establishing tolerances, § 406 does not require FDA to establish them for all added poisonous or deleterious substances that are required in food production or that cannot be avoided by good manufacturing practice, *Young v. CNI*, 476 U.S. 974 (1986). And even though § 305 (21 U.S.C. § 335) provides that before FDA reports a violation of the FDCA to a U.S. Attorney for initiation of a criminal proceeding, the person against whom the proceeding is contemplated "shall be given" notice and an opportunity to present his or her views, § 305 does not require FDA to hold a hearing before reporting a criminal violation to the Department of Justice, *United States v. Dotterweich*, 320 U.S. 228, *reh'g denied*, 320 U.S. 815 (1943). See also *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973) (upholding administrative summary judgment in NDA withdrawal proceedings, notwithstanding language in § 505(e) (21 U.S.C. § 355(e)) directing FDA to provide NDA-holder an opportunity for a hearing before ordering withdrawal of approval); paragraph XIV of the order entered by the court in *American Public Health Association v. Veneman,* 349 F. Supp. 1311 (D.D.C. 1972) (allowing continued marketing of medically necessary new drugs the claimed effectiveness of which was not supported by adequate and well-controlled investigations).

By regulation, too, FDA has recognized that statutory pathways and criteria are not the exclusive means of satisfying the requirements of the law. *See e.g.*, 21 C.F.R. § 640.120 (authorizing CBER to approve an exception or alternative to any requirement in 21 C.F.R. Parts 600-680 regarding blood, blood components, or blood derivatives); 21 C.F.R. § 314.90 (authorizing CDER to waive *any* requirement respecting an NDA, including any criteria of an adequate and well-controlled clinical investigation; 21 C.F.R. §§ 801.420 and 801.430 (imposing testing requirements on hearing aid and tampon manufacturers respectively, in the context of labeling under Section 502 of the FDCA rather than performance standards under Section 514).[1]

Thus, FDA has recognized that statutory requirements can be satisfied through diverse means, provided such means are consistent with the congressional intent. The legislative history of the registation and listing provisions of the FDCA indicates that they were intended to facilitate enforcement, enhance inspection capabilities, and promote product safety and performance, purposes that would be met if a foreign-based parent were permitted to register, as well as list, for each of its foreign establishments.

Establishment registration was added to the FDCA by the Drug Amendments of 1962. *See generally*, S. Rep. No.87-1744, *reprinted in* 1962 U.S.C.C.A.N. In explaining the new legislation, the Senate Committee on the Judiciary concluded (*id.* at 2888-89):

> [D]rugs should not be on the market unless the Food and Drug Administration knows who is making them, and where they are being made, and is able to inspect the facilities in which they are being made. This will help to stop illicit and substandard manufacturers who do not follow the methods or establish the controls called for by good manufacturing practice. The registration system...is thus a facet of the additional inspection authority...and the provisions on quality manufacturing controls...

The listing provisions of the FDCA were added to the statute by the Drug Listing Act of 1972, and were likewise intended to enhance FDA's enforcement capabilities. The legislative history shows that Congress concluded that establishment registration was

---

[1] In addition, from 1970 through 1990 FDA authorized -- by regulation -- the "interim" marketing of unapproved new animal drugs containing one or more of certain sulfonamides. *See* 55 Fed. Reg. 32,390, Aug. 9, 1990 and 53 Fed. Reg. 35,833, Sept. 15, 1988 (preamble to proposed and final rules removing 21 C.F.R. § 510.450).

insufficient to enforce the law and that drug listing was required. As the Senate Committee on Labor and Public Welfare put it:

> [U]nder section 510...every establishment engaged in the manufacture...or processing of a drug must register annually....This provides the [FDA] with a complete list of drug establishments but does not permit the [FDA] to determine what drugs are being manufactured and commercially distributed by those establishments. The effective enforcement of the drug provisions of the Act requires the ready availability of a current inventory of all marketed drugs.

S. Rep. No. 92-924, *reprinted in* 1972 U.S.C.C.A.N. 2963, 2964.

Plainly, the purposes of registration, as of listing, would be well served by permitting a foreign-based parent to register as well as list for each of its foreign establishments. This could be accomplished by insering the words "registration and" after the words "except that" in proposed §§ 207.20(a), 607.20(a), and 807.20(a)

II. GOOD SENSE

A single official contact with responsibility for the reliability, accuracy and timeliness of all registration and listing information for each of a parent's foreign establishments would conserve industry and FDA resources -- time and money -- by promoting efficiency and consistency and by facilitating the development of a single unified registration and listing system. By contrast, none of these gains could ever be realized by *requiring* that registration be done by each establishment on its own. Indeed, simple logic dictates that the greater the number of people and organizations involved in providing registration and listing information to FDA, the greater the likelihood that the data will be inconsistent, unreliable, inacurate, and untimely -- and that the agency will need to devote a disproportionate amount of its resources to data correction.

III. U.S. AGENT

We believe that the proposed duties of the U.S. agent (proposed §§ 207.40(c)(2), 607.40(d)(2), and 807.40(b)(2)), flexible as they are, are reasonable and constitute a vast improvement over the "command and control" approach reflected in current § 807.3(r), as stayed by notice published in the Federal Register of July 23, 1996 (61 Fed. Reg 38,345).

We accordingly recommend that FDA finalize proposed §§ 207.40(c)(2), 607.40(d)(2), and 807.40(b)(2) as proposed.

Respectfully submitted,

Michael M. Landa

4042.01 .DC (34@01!.DOC)
07/27/99 1:58 PM